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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,262	03/14/2002	Mie Takahashi	2001-1890A	1310

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EXAMINER

THERKORN, ERNEST G

ART UNIT PAPER NUMBER

1723

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/019,262

Applicant(s)

TAKAHASHI ET AL.

Examiner

Ernest G. Therkorn

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 $\square$  may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,497,842 in view of each of Nakaya (Japan Patent No. 11-044689), Mochizuki (Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817). At best, the claims differ from claims 1-29 of U.S. Patent No. 6,497,842 in reciting two regions that the liquid impermeable sheet material does not cover. Nakaya

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(Japan Patent No. 11-044689) (Abstract) discloses spaces 9 in the coloring region, in addition to the sample addition region, enhance detection accuracy. Mochizuki (Japan Patent No. 10-332,700) (Abstract) discloses use of a hole in addition to the sample addition region for venting air. Takahashi (Japan Patent No. 11-094,817) (Abstract) discloses tearing off portions of the moisture proof sheet for sample addition and as a confirmation window. It would have been obvious to use a second region in claims 1-29 of U.S. Patent No. 6,497,842 either because Nakaya (Japan Patent No. 11-044689) (Abstract) discloses spaces 9 in the coloring region, in addition to the sample addition region, enhance detection accuracy; or because Mochizuki (Japan Patent No. 10-332,700) (Abstract) discloses use of a hole in addition to the sample addition region for venting air; or because Takahashi (Japan Patent No. 11-094,817) (Abstract) discloses tearing off portions of the moisture proof sheet for sample addition and as a confirmation window.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

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patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over that which is conceded to be old on pages 1-4 of the specification in view of each of Nakaya (Japan Patent No. 11-044689), Mochizuki (Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817). At best, the claims differ from that which is conceded to be old on pages 1-4 of the specification in reciting use of a liquid impermeable sheet and two regions that the liquid impermeable sheet material does not cover. Nakaya (Japan Patent No. 11-044689) (Abstract) discloses a laminate protects the chromatographic strip. Nakaya (Japan Patent No. 11-044689) (Abstract) discloses spaces 9 in the coloring region, in addition to the sample addition region, enhance detection accuracy. Mochizuki (Japan Patent No. 10-332,700) (Abstract) discloses a moisture impermeable film allows the chromatographic test strip to be carried, handled, kept, and preserved after reaction. Mochizuki (Japan Patent No. 10-332,700) (Abstract) discloses use of a hole in addition to the sample addition region for venting air. Takahashi (Japan Patent No. 11-094,817) (Abstract) discloses that a moistureproof sheet allows the test strip to be preserved for a long time. Takahashi (Japan Patent No. 11-094,817) (Abstract) discloses tearing off portions of the moisture proof sheet for sample addition and as a confirmation window. It would have been obvious to use a liquid impermeable sheet either because Nakaya (Japan Patent No. 11-044689) (Abstract) discloses a laminate protects the chromatographic strip, or because Mochizuki (Japan Patent No. 10-332,700) (Abstract) discloses a moisture impermeable

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film allows the chromatographic test strip to be carried, handled, kept, and preserved after reaction, or because Takahashi (Japan Patent No. 11-094,817) (Abstract) discloses that a moistureproof sheet allows the test strip to be preserved for a long time. It would have been obvious to use a second region in which is conceded to be old on pages 1-4 of the specification either because Nakaya (Japan Patent No. 11-044689) (Abstract) discloses spaces 9 in the coloring region, in addition to the sample addition region, enhance detection accuracy; or because Mochizuki (Japan Patent No. 10-332,700) (Abstract) discloses use of a hole in addition to the sample addition region for venting air; or because Takahashi (Japan Patent No. 11-094,817) (Abstract) discloses tearing off portions of the moisture proof sheet for sample addition and as a confirmation window.

Claims 18-35 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Nakaya (Japan Patent No. 11-044689), Mochizuki (Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817). The claims are considered read on each of Nakaya (Japan Patent No. 11-044689), Mochizuki (Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817). However, if a difference exists between the claims and each of Nakaya (Japan Patent No. 11-044689), Mochizuki (Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817), it would reside in optimizing the elements of each of Nakaya (Japan Patent No. 11-044689), Mochizuki (Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817). It would have been obvious to optimize the elements of each of Nakaya (Japan Patent No. 11-044689), Mochizuki

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(Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817) to enhance separation.

The remarks urge that the double patenting rejection is improper because the modification of U.S. Patent No. 6,497,842 would render the device unsuitable for its intended purpose. However, modifying claims 1-29 of U.S. Patent No. 6,497,842 to use a second region in claims 1-29 of U.S. Patent No. 6,497,842 would enhance claims 1-29 of U.S. Patent No. 6,497,842 either because Nakaya (Japan Patent No. 11-044689) (Abstract) discloses spaces 9 in the coloring region, in addition to the sample addition region, enhance detection accuracy; or because Mochizuki (Japan Patent No. 10-332,700) (Abstract) discloses use of a hole in addition to the sample addition region for venting air; or because Takahashi (Japan Patent No. 11-094,817) (Abstract) discloses tearing off portions of the moisture proof sheet for sample addition and as a confirmation window.

The remarks urge that the disclosure on pages 1-4 of the specification is not conceded to be old. However, labeling the section "Background Art" and extensive use of the words "conventional" and "conventionally" is sufficient to concede the subject matter to be prior art.

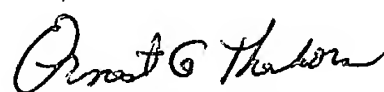
The remarks urge each of Nakaya (Japan Patent No. 11-044689), Mochizuki (Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817) does not disclose two regions that the liquid impermeable sheet material does not cover. However, Nakaya (Japan Patent No. 11-044689) (Abstract) discloses spaces 9 in the coloring region, in addition to the sample addition region, enhance detection accuracy.

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Mochizuki (Japan Patent No. 10-332,700) (Abstract) discloses use of a hole in addition to the sample addition region for venting air. Takahashi (Japan Patent No. 11-094,817) (Abstract) discloses tearing off portions of the moisture proof sheet for sample addition and as a confirmation window. As such, two regions that the liquid impermeable sheet material does not cover are considered to be disclosed by each of Nakaya (Japan Patent No. 11-044689), Mochizuki (Japan Patent No. 10-332,700), and Takahashi (Japan Patent No. 11-094,817).

The remarks urge patentability based upon the omission of a water absorption part. However, the open format of the claims does not preclude the use of a water absorption part.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is (703) 872-9306.



**Ernest G. Therkorn**  
**Primary Examiner**  
**Art Unit 1723**

EGT  
January 30, 2004